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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/798,218      | 03/10/2004  | Marcel Thurk         | 02198/0200973-US0   | 3485             |

7278 7590 03/31/2005

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EXAMINER

KOSAR, ANDREW D

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1654

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |  |                                      |  |
|------------------------------|--|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/798,218     | <b>Applicant(s)</b><br>THURK, MARCEL |  |
|                              | <b>Examiner</b><br>Stephen J. Lee, Ph.D. | <b>Art Unit</b><br>1654              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.  
4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 91, 117, 118, and 124 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☒ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/11/04</u> . | 6) <input type="checkbox"/> Other: ____  |

**Continuation of Disposition of Claims:** Claims pending in the application are 1,17-19,23-26,50-52,56-59,82-84,88-91,117-119,123-126,163-165 and 169-171.

**Continuation of Disposition of Claims:** Claims withdrawn from consideration are 1,17-19,23-26,50-52,56-59,82-84,88-90,119,123,125,126,163-165 and 169-171.

### DETAILED ACTION

Applicant's election without traverse of Group IV containing claims 91, 117, 118, and 124 in the reply filed on February 28, 2005 is acknowledged. In response to the restriction/election of species requirements, applicants have elected the following consecutive peptide sequence as their species election: hydrogen, (chemical bond), alanine, (D)cyclohexylalanine, (L)azetidine-2-carboxylic acid, (D)tyrosine, (L)homoarginine, an amino group. Currently, claims 1,17-19,23-26,50-52,56-59,82-84,88-91,117-119,123-126,163-165 and 169-171 are pending, claims 2-16, 20-22, 27-49, 53-55, 60-81, 85-87, 92-116, 120-122, 127-162, and 166-168 are cancelled, and claims 1,17-19,23-26,50-52,56-59,82-84,88-90,119,123,125,126,163-165 and 169-171 are withdrawn.

### ***Priority***

The instant application is a continuation of PCT/EP02/10137, and claims benefit of foreign priority date.

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) or 120 as follows: The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077

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(Fed. Cir. 1994). In the instant application, recitations of claims 91, 117, 118, and 124 are not disclosed in the foreign application, Germany 101 44 340.4. Therefore, the instant application can not claim benefit to foreign priority date of September 10, 2001.

### ***Abstract***

The abstract of the disclosure is objected to because in the second line, the words "...general formula (I)" is used. In the instant application, formula (I)-formula (V) are claimed. While their generic formula is the same, i.e.  $Y^1-(NH-X^1-C=O)-(NH-X^2...$ , their definitions are not, compare e.g.  $(NH-X^1-C=O)$  of claim 91 to claim 126. The examiner recommends that "(I)" is deleted in the second line to avoid confusion. Correction is required. See MPEP § 608.01(b).

### ***Duplicate Claims***

Applicant is advised that should claim 117 be found allowable, claim 124 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 91 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 91 recites the broad recitation "...wherein (NH-X<sup>1</sup>-C=O) is a D- or L-amino acid, preferably", and the claim also recites specific amino acids, as defined by a) – m) under "...wherein (NH-X<sup>1</sup>-C=O) is a D- or L-amino acid, preferably", which is the narrower statement of the range/limitation.

Claims 117, 118, and 124 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly

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claim the subject matter which applicant regards as the invention. Claims 117, 118, and 124 are indefinite because they all depend on claim 91, which is indefinite as explained above.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 91, 117, 118, and 124 are rejected under 35 U.S.C. 102(b) as being anticipated by Coughlin (US 6197541 B1). In the instant claim 91, applicants claim a compound of formula (IV). Because of the open language used to specify the  $\text{NH-X}^1\text{-C=O}$  to  $\text{NH-X}^6\text{-C=O}$ , in addition to the specifications recited in claim 91, examiner interprets this as encompassing other amino acids not recited in claim 91. In view of this, Coughlin teaches thrombin inhibiting peptides which meet the limitations of what is recited in the instant claim 91, see col. 3, lines 1-18, and col. 11, lines 51-67. Furthermore, Coughlin teaches that these peptides can be used pharmaceutically (see col. 3, lines 47-58) and diagnostically (see Abstract).

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***Examiner Notes***

The elected peptide sequence species: hydrogen-(chemical bond)-alanine-(D)cyclohexylalanine-(L)azetidine-2-carboxylic acid-(D)tyrosine-(L)homoarginine-an amino group was searched and no prior art was found.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen J. Lee whose telephone number is 571-272-3446. The examiner can normally be reached on M-F; 9a.m.-6p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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